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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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10/784,807

02/24/2004

Mark Gelfand

LE-218J

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| EXAMINER |
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MATTHEWS, WILLIAM H

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| ART UNIT | PAPER NUMBER |
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3774

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10/25/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/784,807

Applicant(s)

GELFAND ET AL.

Examiner

William H. Matthews (Howie)

Art Unit

3774

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-61 and 64-97 is/are pending in the application.
- 4a) Of the above claim(s) 12-16, 19, 35-44, 53-57, 60 and 67-97 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 21-34 is/are allowed.
- 6) ☒ Claim(s) 1-11, 17, 18, 20, 45-52, 58, 59, 61 and 64-66 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

Response to Arguments

Applicant's arguments filed 8-2-07 have been fully considered but they are not persuasive.

Regarding Guiset, Applicant contend Guiset fails to "maintain" the increased pressure as claimed (and therefore lacks reducing a renal function), and further that Guiset lacks any disclosure of surgery. Examiner respectfully disagree. The claimed step of "maintaining the increased pressure" lacks a requirement of a specified period of time. Furthermore, Guiset may be interpreted to provide increased pressure from the point in time at which pressure is increased until the point in time in which the pressure returns to baseline. Regarding surgery, column 5 line 60 through column 6 line 28 describe multiple "surgeries" which may be performed.

Regarding Cionata et al., Applicant contend the urine drainage port prevents pressure from increasing within the urinary tract as claimed. Examiner respectfully disagree. Independent claims 1 and 45 each recite the step of "artificially increasing pressure (or a pressure, claim 45) in a urinary tract of at least one kidney of the patient". This limitation is readily on any pressure being increased within the urinary tract (or within the bladder as required by certain dependent claims). A renal function is reduced in Cioanta et al. because, as depicted in the figures, the increased pressure in the anchoring balloon blocks natural urine flow.

Election/Restrictions

This application contains claims 12-16,19,35-44,53-57,60, and 67-97 drawn to an invention nonelected with traverse in the reply filed 1-16-07 and noted in the Office Action mailed 4-10-07. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Objections

1. Claim 45 is objected to because of the following informalities: in line 1, "comprising" should be inserted. Appropriate correction is required.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1-3,7-10,17,18,20,45-47,49-51,58,59,61,64,65 are rejected under 35 U.S.C. 102(b) as being anticipated by Guiset US PN 4044401.
4. Guiset et al. disclose in figure 1 and corresponding description a method of protecting a kidney or inhibiting a natural function of a kidney during surgery comprising

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artificially increasing pressure (by mere placement of balloon 27 or inflation by reservoir 23) which reduces or inhibits natural renal function and thereafter reducing pressure.

Note the method disclose may be utilized in a natural bladder rather than artificial rigid bladder 6.

5. Claims 1-3,5,6-11,17,18,20,45-47,49-52,58,59,61,64-66 are rejected under 35 U.S.C. 102(e) as being anticipated by Cioanta et al. US PN 6682555.

6. Cioanta et al. disclose a method of protecting a kidney or inhibiting a natural function of a kidney during surgery comprising artificially increasing pressure (by inflation of balloon 15 or 52, see figure 10B) which reduces or inhibits natural renal function and thereafter reducing pressure. Column 14, line 41 through column 15 line 28 disclose various contrast agents which may be delivered after pressure within the urinary tract is increased.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 4,48,62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guiset US PN 4044401.

9. Guiset disclose the limitations of claims 4,48, and 62 as described above but lack the express written disclosure of increasing the pressure to about 15 cmH2O.

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However, Guiset disclose pressure created by pressing on reservoir 23 causing fluid 24 to inflate balloon 27 thereby increasing pressure inside the bladder in order to open the collar 16 and release urine. The pressure created must be sufficient to overcome a normally closed collar 16. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method disclosed by Guiset to provide a required pressure of at least about 15 cmH2O to open the collar in order to ensure the collar remain closed when urination is not required.

Allowable Subject Matter

10. Claims 21-34 are allowed.

11. The following is a statement of reasons for the indication of allowable subject matter: the prior art of record fail to disclose or substantially render obvious a method of preventing or treating contrast nephropathy inpatients undergoing radiographic procedures comprising the steps of increasing pressure in a urinary tract, injecting contrast agent into a blood vessel, and reducing pressure in the urinary tract.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Matthews (Howie) whose telephone number is 571-272-4753. The examiner can normally be reached on Monday-Friday 10-6:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M. McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/William H. Matthews/
Primary Examiner
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